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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/550,287	09/22/2005	Hideaki Yamaoka	10873.1753USWO	9535
52835 7590 03/03/2009 HAMRE, SCHUMANN, MUELLER & LARSON, P.C. P.O. BOX 2902			EXAMINER	
			GEHMAN, BRYON P	
MINNEAPOLIS, MN 55402-0902			ART UNIT	PAPER NUMBER
			3728	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)			
Office Action Comments	10/550,287	YAMAOKA, HIDEAKI			
Office Action Summary	Examiner	Art Unit			
	Bryon P. Gehman	3728			
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply					
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).					
Status					
1)⊠ Responsive to communication(s) filed on <u>09 Ja</u>	nuary 2009				
	action is non-final.				
·=	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is				
	closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.				
		0 0.0. 2.0.			
Disposition of Claims					
<ul> <li>4) ☐ Claim(s) 10,11,13,16,17 and 19-28 is/are pending in the application.</li> <li>4a) Of the above claim(s) is/are withdrawn from consideration.</li> <li>5) ☐ Claim(s) is/are allowed.</li> <li>6) ☐ Claim(s) 10,11,13,16,17 and 19-28 is/are rejected.</li> <li>7) ☐ Claim(s) is/are objected to.</li> <li>8) ☐ Claim(s) are subject to restriction and/or election requirement.</li> </ul>					
Application Papers					
<ul> <li>9) The specification is objected to by the Examiner.</li> <li>10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.  Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).</li> <li>11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.</li> </ul>					
Priority under 35 U.S.C. § 119					
<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>					
Attachment(s)    Notice of References Cited (PTO-892)					

Application/Control Number: 10/550,287 Page 2

Art Unit: 3728

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 2. Claims 10, 13, 16-17 and 19-28 are finally rejected under 35 U.S.C. 103(a) as being unpatentable over JP 2001141686.in view of Stewart et al. (4,589,547), one of Heller et al. (6,143,164) and Mao et al. (6,605,201) and Feldman et al. (6,461,496). JP 2001141686 discloses a sensor-container combination comprising a container including a container body (3), and a plurality of sensors stored in the container. Stewart et al. disclose providing a container (30) that has a transparent container body to allow viewing of the content of the container, with a non-transparent lid (33ba). To modify the container of JP 2001141686 employing the transparent container body and nontransparent lid teaching of Stewart et al. would have been obvious in order to allow visual assertion of the content of the sensor container, as suggested by Stewart et al., and closing of the container for shipping. The provision of portion of transparency as opposed to entire transparency is considered an obvious matter of choice and degree, the differences provided not being new or unobvious to one of ordinary skill in the art. "A combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." KSR Int 'I v. Teleflex Inc., 127 S.Ct. 1731, 82 USPQ2d at 1396. Heller et al. and Mao et al. each disclose a sensor including an oxidation-reduction enzyme, a mediator that mediates transfer of electrons

Art Unit: 3728

caused by oxidation or reduction, and a detection means that detects a reaction of the oxidation or reduction, a sensor that was previously known in the filed of biosensors. To employ sensors having the properties described above in the modified container combination would have been an obvious substitution of equivalent sensors in the combination. Feldman et al. further discloses sensors that are composed of materials resistant to ultraviolet light, therefor having inherent lightfastness. To modify the claimed container of JP 2001141686 employing a particular sensor therein would have been obvious, the choice alterations to the sensor such as per one of Heller et al. and Mayo et al. and Feldman et al. being an obvious substitution to one of ordinary skill in the art in order to derive the advantages of a particular sensor per se in the claimed sensor-container combination.

As to claim 19, Stewart et al. discloses a circular shape for the container. To modify the shape of any container to the cross-sectional shape of its intended contents as claimed would entail a mere change in shape of the container and yield only predictable results. "[I]f a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond that person's skill." *KSR Int'l v. Teleflex Inc.*, 127 S.Ct. 1740, 82 USPQ2d 1396 (2007). A change in form or shape is generally recognized as being within the level of ordinary skill in the art, absent any showing of unexpected results. *In re Dailey et al.*, 149 USPQ 47.

As to claim 20, to provide the container body and lid of a conventional hinged arrangement would have been obvious in order to maintain the container body and lid in conjunction for ease of reclosing of the container body, as is conventional knowledge to one of ordinary skill in the art.

As to claim 21, to provide the container of particular color is a design consideration only, and does not distinguish any new or unexpected utility by its selection in and of itself.

- 3. Claim 11 is finally rejected under 35 U.S.C. 103(a) as being unpatentable over the art as applied to claim 10 above, and further in view of either one of Yamamoto et al. (4,889,229) and Swain (3,139,976). The previous combination does not provide for a scale indicating the amount of contents in the container. Yamamoto et al. and Swain each disclose providing a container (11; 11; respectively) that is transparent and provided with a scale (15; 17 and 18) to allow viewing and determining the remaining content of the container. To modify the container of the previous combinations employing the scaled transparent container teaching of either one of Yamamoto et al. and Swain would have been obvious in order to ascertain the remaining content of the sensor container, as suggested in general for contents by either one of Yamamoto et al. and Swain.
- 4. Claims 24-25 and 27-28 are further finally rejected under 35 U.S.C. 103(a) as being unpatentable over the art as applied to claims 10 and 22 above, and further in

Application/Control Number: 10/550,287

Art Unit: 3728

view of Karinka et al. (2004/0079653). The prior combination of art does not expressly define ammonia serving as a nitrogen associated with a ligand in a biosensor. To any degree the generic nitrogen-containing ligand of Feldman et al. would not obviously include ammonia as a nitrogen, Karinka et al. further discloses a biosensor united with a ammonia –containing ligand (see paragraph 0041). It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a sensor of the claimed sensor-container combination with an ammonia-containing ligand as claimed, as such a modification would predictably serve the purpose intended therefor as disclosed by Karinka et al. to provide an advantageous sensor. "A combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." *KSR Int 'I v. Teleflex Inc.*, 127 S.Ct. 1731, 82 USPQ2d at 1396.

Page 5

5. Applicant's arguments with respect to claims 10-11, 13-17 and 19-22 have been considered but are moot in view of the new combinations of grounds of rejection. The new grounds are discussed at length above. The particular sensor having an enzyme, a mediator, a detection means and a nitrogen-containing ligand appear to be of conventional structure at the time the claimed combination was derived, indicating the claiming of a particular sensor to be unique, but not providing any apparent new or unexpected result by its particular selection. Furthermore, were the particular sensor be itself of an inventive nature, such would have been individually claimed so from the start or subject of a patent application, not merely a particular sensor disposed in a container

Application/Control Number: 10/550,287

Page 6

Art Unit: 3728

combination, which generic sensor and container was the apparent basis of the inventive concept. The further limitation of the sensor in particularity is not seen to render the claimed combination new or unobvious.

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Feldman et al. (6,299,757) shows a sensor similar in many respects, if not all, that are claimed.

Art Unit: 3728

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bryon P. Gehman whose telephone number is (571) 272-4555. The examiner can normally be reached on Tuesday through Thursday from 7:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mickey Yu, can be reached on (571) 272-4562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bryon P. Gehman/ Primary Examiner, Art Unit 3728

Bryon P. Gehman Primary Examiner Art Unit 3728

**BPG**